

PATENT COOPERATION TREATY
PCT
INTERNATIONAL SEARCH REPORT
(PCT Article 18 and Rules 43 and 44)

| | | |
|--|---|--|
| Applicant's or agent's file reference 12531680/EJH/JEH/RBR | FOR FURTHER ACTION | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
| International application No. PCT/AU2004/001522 | International filing date (<i>day/month/year</i>) 5 November 2004 | (Earliest) Priority Date (<i>day/month/year</i>) 7 November 2003 |
| Applicant HEPGENICS PTY LTD et al | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of **6** sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box No. II).

3. ☐ Unity of invention is lacking (See Box No. III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☒ none of the figures is to be published with the abstract.

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

international application No.
PCT/AU2004/001522**Box No. II** Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 1-65 (in part)
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Due to the broad scope of the claims (ie in particular the scope of the detection marker-analyte binding partner complex), the search was necessarily restricted to the preferred embodiments and the disclosed examples, for which there was descriptive support.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/001522

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. G01N 33/58, 33/566, 33/577, C07K 17/14, C12Q 1/68, 1/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

STN: MEDLINE, BIOSIS, WPIDS, Chem Abs; keywords based on monoclonal antibody, colloidal gold, detect, mannose

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | EP 1 035 414 A2 (MADAUS AG) 13 September 2000 (& Derwent Abstract Accession No. 2000-595496/57, Class B04 D16, EP 1035414 A2) See especially the claims, examples and Fig. 1 | 1-65 |
| X | WERTHEN M et al: "Effect of antibody affinity on the isotherm of antibody binding to surface-immobilized antigen"; Journal of Immunological Methods, 115 (1988) 71-78 See whole document | 1-65 |
| X | MOORE N et al: "Development of a Panel of Rapid Tests for Viral Respiratory Diseases"; Abstracts of the General Meeting of the American Society for Microbiology, (May 2003), Vol. 103, pp C-356 See abstract | 1-65 |

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

| | |
|---|--|
| * Special categories of cited documents: | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier application or patent but published on or after the international filing date | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | |
| "P" document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search
16 December 2004

Date of mailing of the international search report 06 JAN 2005

Name and mailing address of the ISA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No. (02) 6285 3929Authorized officer
G. D. HEARDER
Telephone No. (02) 6283 2553

BEST AVAILABLE COPY

| C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|---|--|-----------------------|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | Lea P et al: "Advantages of Backscatter Electron Imaging Scanning Electron Microscopy for Intracellular Localization of Cardiac Analytes by Gold Conjugated Antibody"; Scanning (1996) Vol. 18, 259-68 See whole document | 1-65 |
| X | Paek SH et al: "Development of rapid one-step immunochromatographic assay"; Methods 2000 Sep, 22(1): 53-60 See whole document | 1-65 |
| X | Haftek M et al: "Immunogold Labeling of Keratin Filaments in Normal Human Epidermal Cells With Two Anti-keratin Monoclonal Antibodies"; The Journal of Histochemistry and Cytochemistry 1986, Vol. 34, No. 5, pp 613-618 See whole document | 1-65 |
| X | PEI R et al: "Amplification of antigen-antibody interactions based on biotin labeled protein-streptavidin network complex using impedance spectroscopy."; Biosensors & Bioelectronics 2001, 16: 355-61. See whole document | 1-65 |
| X | WU S J et al: "Comparison of two rapid diagnostic assays for detection of immunoglobulin M antibodies to dengue virus."; Clinical And Diagnostic Laboratory Immunology, (2000 Jan) 7 (1) 106-10 See whole document, especially p 106-107 | 1-65 |
| X | VAUGHN D W et al: "Evaluation of a Rapid Immunochromatographic Test for Diagnosis of Dengue Virus Infection"; Journal of Clinical Microbiology, Jan. 1998, p 234-238 See whole document, especially p 235 (PanBio Dengue Rapid Test) | 1-65 |
| X | BASTHOLM L et al: "Simultaneous demonstration of two antigens in ultrathin cryosections by a novel application of an immunogold staining method using primary antibodies from the same species"; Histochemistry (1987) 87(3):229-231 See whole document | 1-65 |
| X | WO 2003/020204 A2 (SYRACUSE BIOANALYTICAL INC & CORNELL RESEARCH FOUNDATION INC) 13 March 2003 See whole document | 1-65 |
| P, X | PIEPER-FÜRST U et al.: "Detection of subpicomolar concentrations of human matrix metalloproteinase-2 by an optical biosensor"; Analytical Biochemistry (1 September 2004) 332 (1) pp 160-167 See whole document | 1-65 |
| P, X | ZHOU P et al.: "Nanocolloidal Gold-Based Immunoassay for the Detection of the N-Methylcarbamate Pesticide Carbofuran"; Journal of Agricultural and Food Chemistry, (14 July 2004), 52 (14), pp 4355-4359 See whole document | 1-65 |
| P, X | WO 2004/014220 A2 (N-DIA INC) 19 February 2004 See whole document | 1-65 |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/001522

| C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|--|-----------------------|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| P, X | WO 2003/105899 A1 (NEUROPRO TECHNOLOGIES INC) 24 December 2003 See whole document | 1-65 |
| P, X | WO 2003/093793 A2 (TRELLIS BIOSCIENCE INC) 13 November 2003 See whole document | 1-65 |

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU2004/001522

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | | Patent Family Member | |
|---|-------------|------|----------------------|---------------|
| EP | 1035414 | NONE | | |
| WO | 2003/020204 | EP | 1423543 | US 2003143573 |
| WO | 2004/014220 | NONE | | |
| WO | 2003/105899 | US | 2004002168 | |
| WO | 2003/093793 | US | 2004033519 | |

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

BEST AVAILABLE COPY